A vision to 'Design out' accidentally retained surgical items in vaginal childbirth

Ahmed ElGharably[1], Kiran Desai[2], Aaron Vance[3], Jon Lester [4], Emma Bonfiglio[5], Colin Rigby[6], Andrew Forrester[7], Prof Peter Ogrodnik[8], Jeffrey Faint[9], Prof Tom Clutton-Brock[10], Aditi Desai[11]

[1] The Royal Wolverhampton NHS Trust, [2]Eureka Inventions Ltd, [3]University of Wolverhampton, [4]University of Wolverhampton, [5]Keele University, [6]Keele University, [7]Manufacturing Technology Centre, [8]Keele University, [9] NIHR Trauma Management MedTech Co-operative MD-Tec (Medical Devices Testing and Evaluation Centre), [10]NIHR Trauma Management MedTech Co-operative MD-Tec (Medical Devices Testing and Evaluation Centre), [11]The Royal Wolverhampton NHS Trust

SUMMARY

Retained vaginal swabs are a well-recognised and recurrent patient safety 'never event' with the potential to cause significant morbidity. Surgical swabs and surgical tampons, which are considered a type of surgical swab, are the single largest retained item. There have been 340 incidents of retained vaginal swabs reported in England (2012-2022) and underreporting of these incidents is known. The current practice of manual counting is prone to human error and demonstrates a lack of efficacy in dealing with this issue. A simple, cost-effective device was developed collaboratively based on human factors/ ergonomics principles. This is designed to help users focus on the largest problem space, functioning as a physical checklist and memory aid for accurate counting. The team adopted a systems thinking approach to develop the innovation, progressing through steps such as hierarchical task analysis and human factors systems analysis through the SEIPS framework, AcciMap, barrier analysis and user-centred iterative design. The near-manufacture prototype was user-tested in simulation, and results indicate that the device has the potential to facilitate accurate counts in a time-efficient manner. We acknowledge that there will be a need for training, and culture change for the adoption of design solutions in the current workflow. It is known that around 94% of units have electronic records, and software development in order to integrate the device-aided count into electronic medical records with a computer vision app is ongoing. With integration into existing software, the system will not complete the birth episode unless the count tallies. With some additional resources, our vision is to develop and introduce a strong systemic barrier to prevent the problem. Initially, it may be practical to introduce only the device, which acts as a physical checklist and increases system resilience. System engineering tools such as the use of checklists are well-accepted models within patient safety science. However, the role of design which complements human behaviour in achieving system improvement is relatively unknown to healthcare professionals and we intended to explore this.

KEYWORDS

Never event, retained swabs, retained sponges, design, usability, human factors engineering, systems thinking, ergonomics

Introduction

The Healthcare Safety Investigation Branch, UK describes the case of Christine, a 30-year-old woman who had had a vaginal swab inserted after the birth of her first child. It was left in and not discovered until five days after leaving the hospital. Whilst in immense pain throughout, Christine

saw the community midwife and GP twice before going back to the hospital where the swab was found. A retained vaginal sponge/swab is a source of high morbidity, causing pain, discharge, infection, secondary haemorrhage, and psychological harm, particularly affecting mother-baby bonding and, rarely, causing maternal death from sepsis.

There was a realisation that one could move forward through understanding the problem and a re-design of task-tools. Although the initial ideation and early prototyping were born from empathy with the unmet need and heuristics, the innovators realised that a deeper insight was essential to bring the idea to fruition. One innovator returned to University to study a Human Factors-Ergonomics qualification. The team of doctors, midwives, maternity support workers, engineers, designers, statisticians and behavioural psychologists were involved in the development. The innovators adopted a systems thinking and Human Factors-Ergonomics led approach to develop the innovation.

Methods adopted:

1. ***Understanding the system:***

- A stakeholder mapping exercise about the unmet need, the need for solutions, the context, culture, workflow and perceptions about the proposed solution concept was undertaken independently by Keele University, Accelerate Associates and Pym's Consultants. In-depth surveys and interviews of 55 stakeholders (midwives, doctors, nurses, hospital managers from NHS and private sector, reputed patient safety charities such as Patient Safety Learning and Healthwatch Lincolnshire, officials from NHS England, NHS Resolution and the Healthcare Safety Investigation Branch) were undertaken. A freedom of information request gathered information from 69 NHS trusts regarding retained swab incidents and methods of prevention employed by these organisations. The data and narratives analysed were collated to inform further development. Keele University also did a research and innovation support project involving a psychologist to understand the possible psychological factors involved.
- Patient Public Involvement keeps the development relevant to people. This was facilitated through NIHR Surgical MIC and Clinical Research Ambassador Group (CRAG), Birmingham.
- Systems Engineering Initiative for Patient Safety (SEIPS 2.0) helped us get a bird's eye view of the system and understand the interactions between the different components of the system, the process and outcomes. We realised how the swab count process is embedded in the work system. This will also help to align possible solutions in the workflow. SEIPS 2.0 is presented in Figure 1.
- The core team, which comprised of clinicians, undertook a hierarchical task analysis (HTA) to understand 'work as done' in real life about the task of counting swabs in vaginal childbirth. HTA was useful for mapping the system, understanding the many superordinate and subordinate tasks involved, cognitive elements during normal vaginal delivery and the possibilities for variance. HTA is similar to process mapping used in quality improvement methodology but provides more granularity. This is presented in Figure 2.

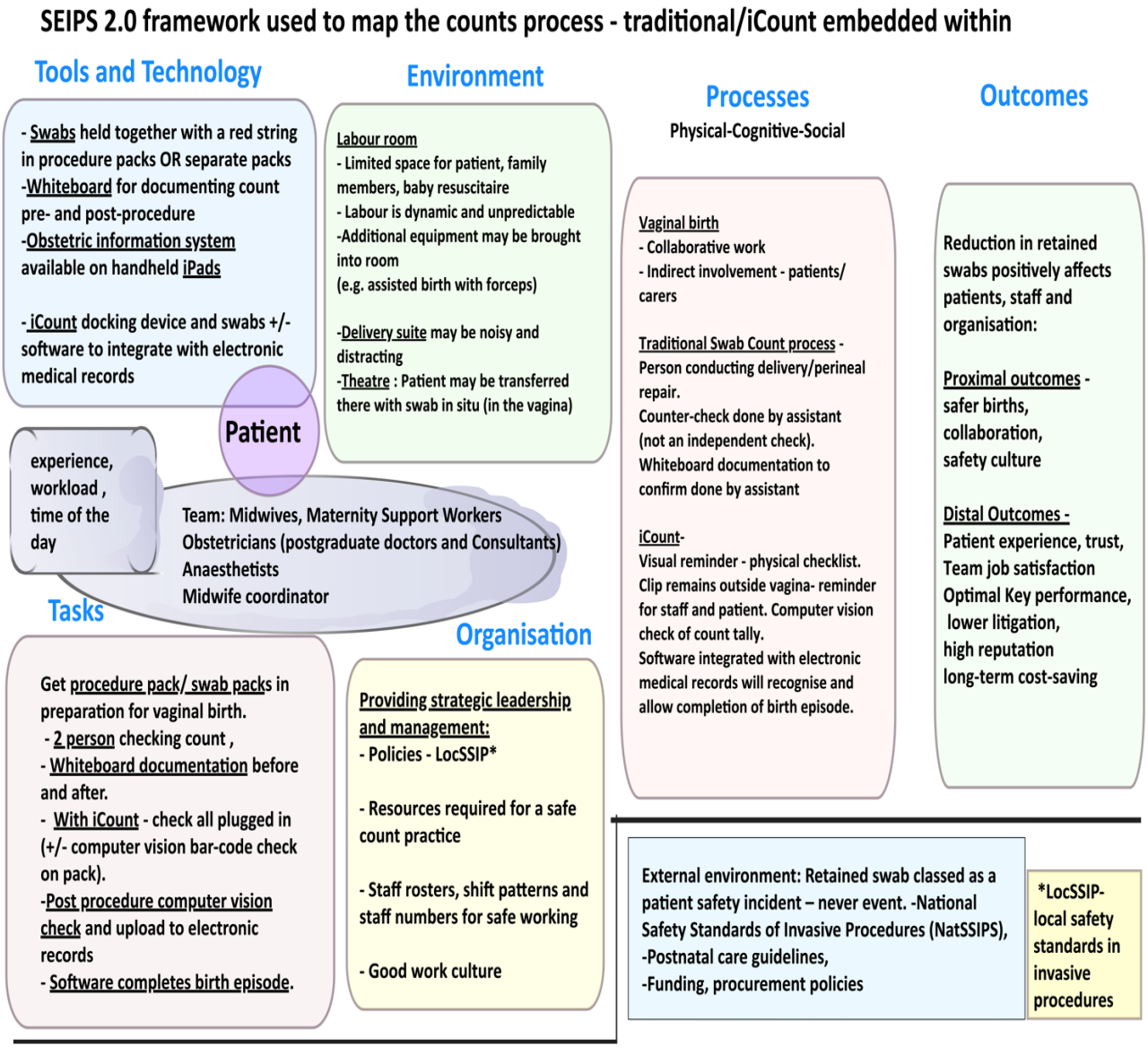

Figure 1: SEIPS 2.0

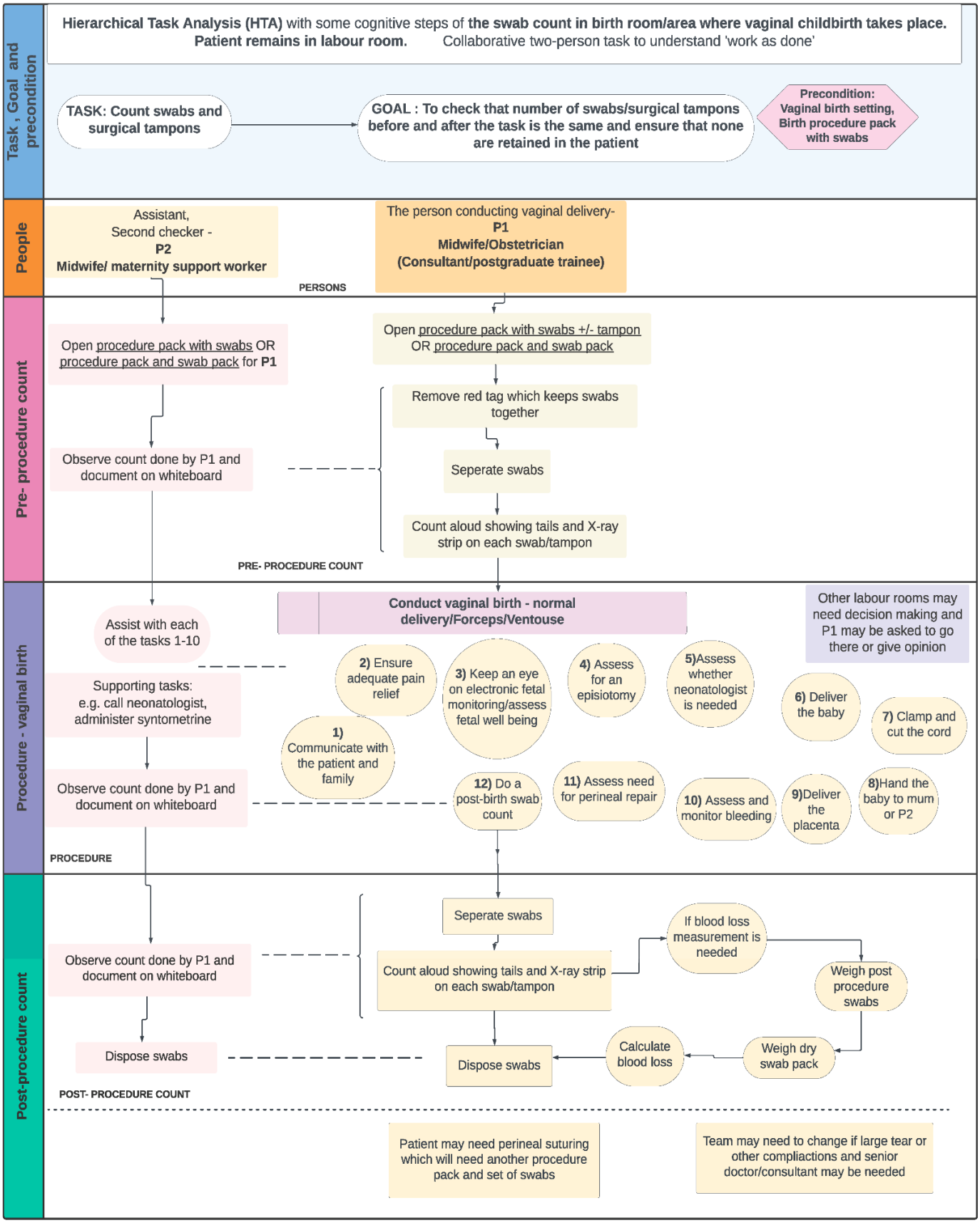

Figure 2: Hierarchical task analysis of the task of counting swabs in vaginal childbirth

HTA also helps to understand the complexity of the task, if and why people have developed workarounds and explore these in a positive way. The HTA done is practical and also includes some cognitive elements. Most of the tasks are presented sequentially. The only exception is that in the vaginal birth procedure, tasks 1 and 2 are carried out throughout, 3 is carried out till the baby is born and 4-12 are done sequentially.

- We used Accident analysis mapping (AcciMap) as a systems-based technique to analyse a real-life incident and understand how factors in the various parts of the system were at play. It also identified some key causative and contributory factors leading to the problem. This is presented in Figure 3.

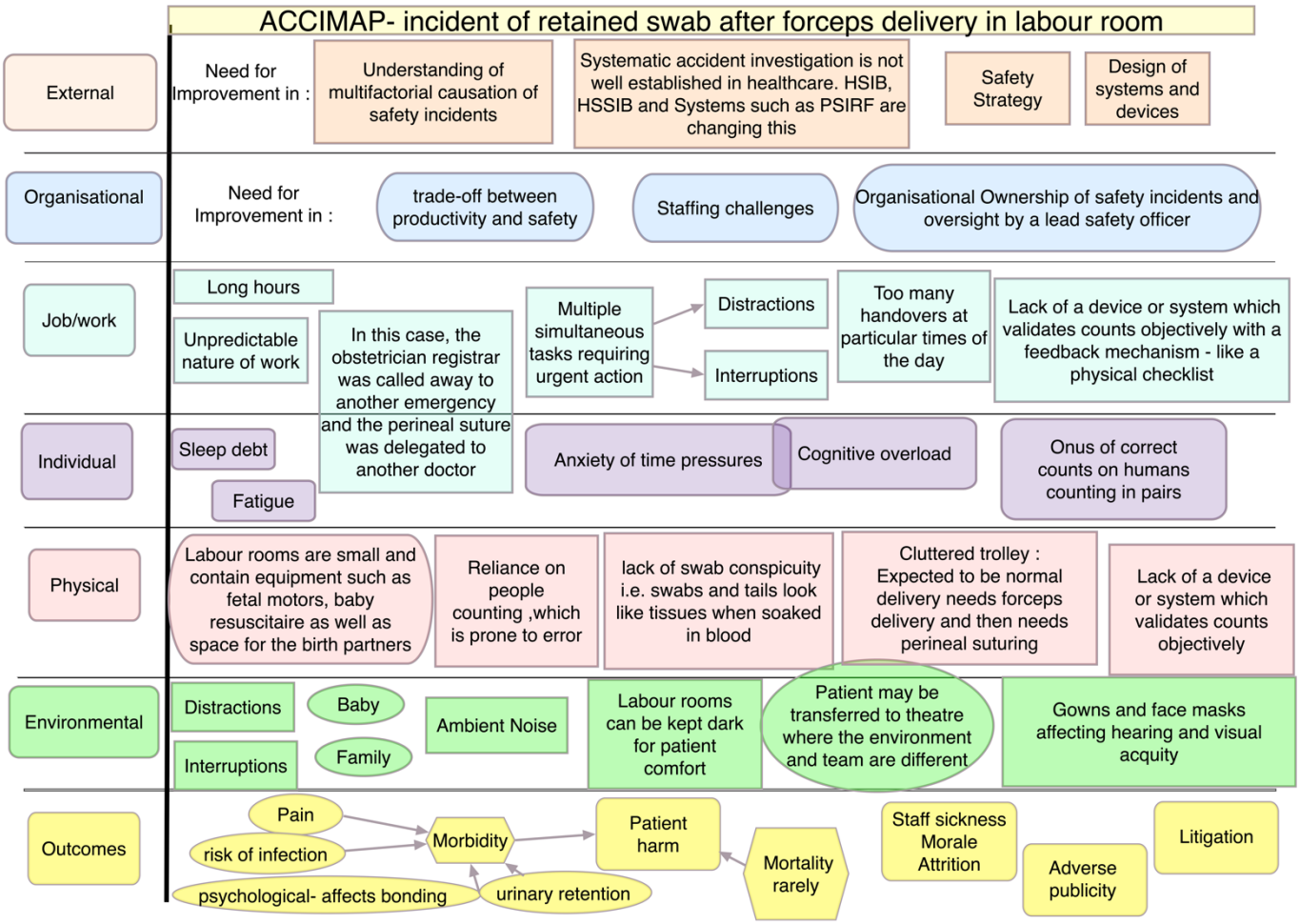

Figure 3: AcciMap

- Barrier Analysis – We used the bow-tie method to understand the controls acting as defences to prevent a hazard (in this case, a retained swab). This analysis is presented in figure 7 for traditional counting method and in figure 8 for iCount.

Design specification of task-tools – The team and the engineers developed the Wardley map. Inclusive design was applied, considering user needs for safety, efficiency, reliability, and ease of use. Consideration was given to unique aspects of the task such as the use of gloves by users, the possibility of colour blindness, right/left-handedness and anthropometrics. Leading to the problem

essential design specifications were derived: 1) The ability to add a signifier to each swab, 2) Ensuring that users have to separate the swabs, 3) Ability to visualise the status of 'the count' at all times, 4) Keeping the counting task in the sterile field since the primary ownership rests with the person conducting childbirth/ perineal repair, 5) User-friendly, 6) Low-cost 7) Compact design i.e. not occupy a large space (ability to stay in a procedure pack/trolley) 8) Environment friendly design - least amount of polyethylene, using environment-friendly plastics, consider reducing swab size from 30x30cm to 20x20cm (user feedback) as cotton has a much higher carbon footprint than plastic. The larger swab size was introduced by most trust after the National Patient Safety Agency (NPSA) alert in 2010 as an attempt to prevent the problem. However, this did not work.

Usability testing in high-fidelity simulation was conducted thrice independently by NIHR MD-Tec (National Institute of Health Research Medical Devices - Technical Evaluation Cooperative) and many times locally and regionally by the team.

Developing strategies to introduce the new design – this work is ongoing. We have also discussed our innovation with Health Services Safety Investigations Body (HSSIB) and sought valuable feedback from them.

***Product developed and user-testing results*:** A simple docking device acts as a physical checklist for accurately counting swabs and displays the current status of that particular task. Environmental sustainability has been considered such that the device and swabs reduce the carbon footprint compared to the current swabs. User testing of the third generation (near manufacture) prototype showed time efficiency compared to traditional two-person manual counts. The majority of users strongly agreed that the device increases user confidence in the accuracy of counts and that this is likely to be a system solution complemented by training and education. The clip security on the tails have had tensile strength testing to higher than the upper limits of ordinary force. The device is undergoing processes needed for regulation. A pre-CE marking clinical study is planned and the innovation will be introduced to the NHS subsequently.

Prototypes Development (18 iterations)– Different designs were developed initially 3D printed, CNC machined, and progressing to injection moulded. Test-iterate-test with multiple feedback cycles and failure modes analysis of prototypes was done.

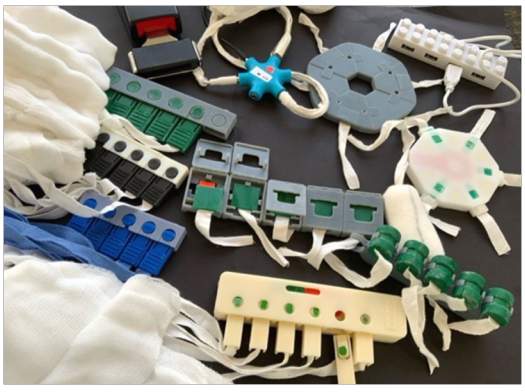

Figure 4: Photo of some of the prototypes

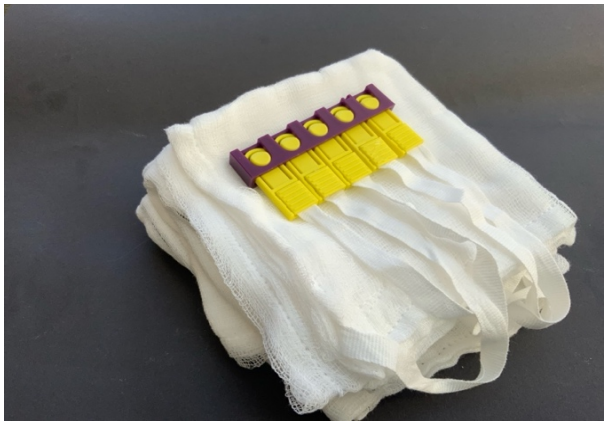

Figure 5: Photo of near-manufacture prototype

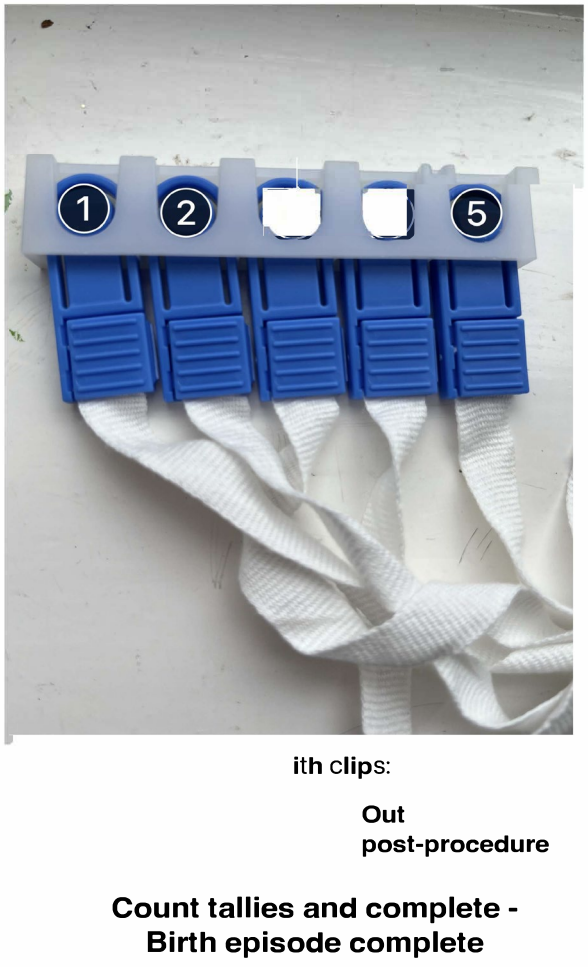

Figure 6: Option of Computer vision/AI software app which can be integrated with electronic medical records

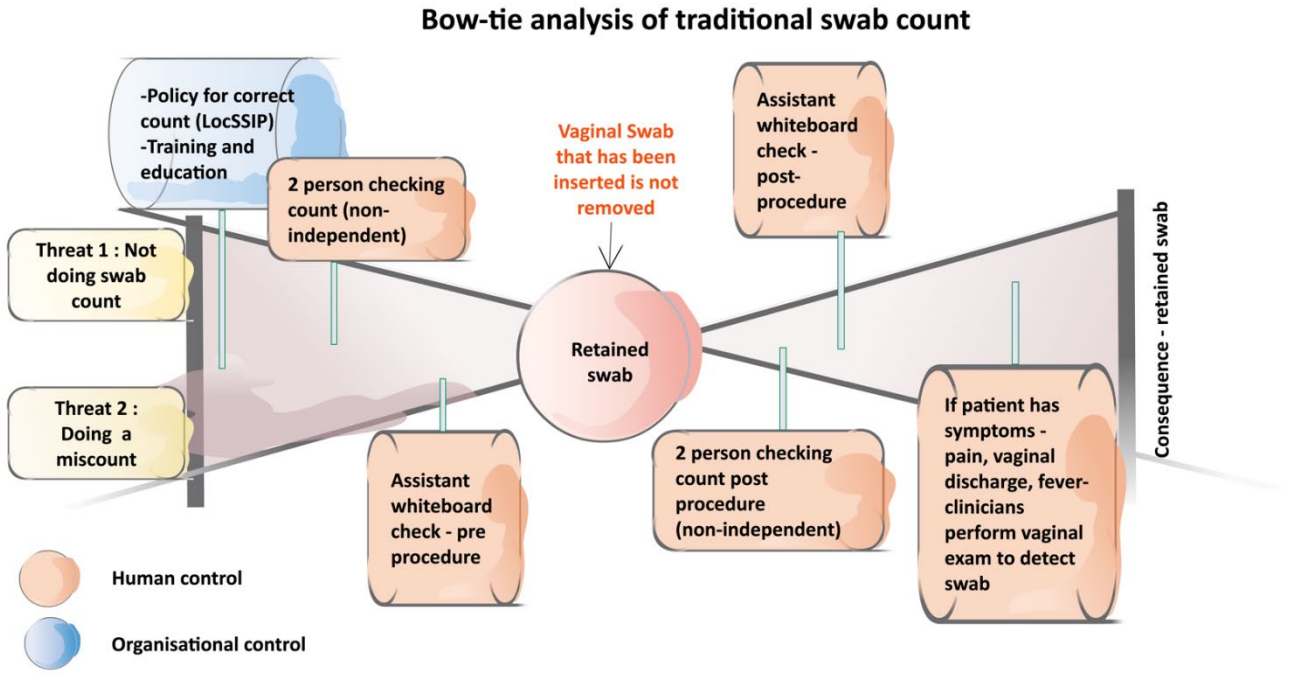

Figure 7: Bow-Tie Barrier Analysis of Counting Practices for Routine swabs and iCount

The threats are events that, if they are not prevented from doing so, will likely lead to the top event occurring. In this case, the threats are – a) not performing a count at all and b) not counting accurately (performing a miscount). The top event is the central knot. On the left side of the knot are controls that are defences that reduce the likelihood of the top event happening, and to the right side are controls that would allow early detection of the incident. Using this method, we can visualise how the controls would work.

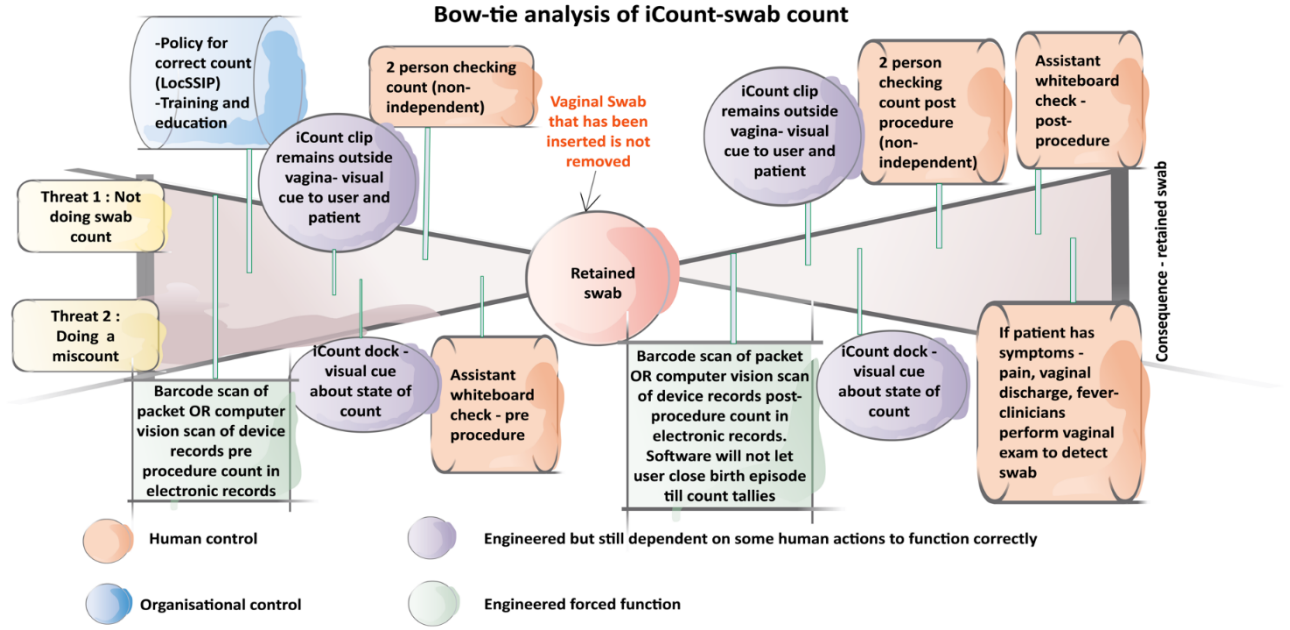

Figure 8: Bow tie analysis

There is a hierarchy in the effectiveness of hazard control, with engineered controls having the highest efficacy and human controls having the lowest. The figures show the barriers in their order of importance, or expected strength, from left to right: Engineered, Organisational and Human.

Discussion

The overarching aim of the human factors and ergonomics discipline is to enable us to adopt a design-driven systems approach to achieve performance and well-being. Retained vaginal swabs are a recurrent 'never event' that leaves women at risk of harm after childbirth. The team has applied these principles to redesign the task and tools to address this. The simulation testing and user testing of the near-final version show staff time saved and encouraging results regarding user confidence.

We acknowledge that there will be a need for training, and culture change for the adoption of design solutions in the current workflow. Initially, it may be practical to introduce only the device, which acts as a physical checklist and increases system resilience. We will be working with electronic medical records providers to move towards a strong systemic barrier with the aim of preventing this problem. This will need some additional resources if we wish to move towards safer care. The introduction of design solutions to work procedures will hopefully encourage other clinicians to work collaboratively on other problems, which are pressing needs within maternity and wider healthcare.

NIHR Statement: This project was supported by the NIHR Trauma Management MedTech Co-operative MD-Tec (Medical Devices Testing and Evaluation Centre). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

References

Healthcare Safety Investigation Branch - (2019). Detection of retained vaginal swabs.
NHS England data. https://www.england.nhs.uk/patient-safety/never-events-data/
James Reason (1991) Human Error.
Charles Vincent (2010) Patient Safety.
Chartered Institute of Ergonomics and Human Factors (2018). White paper- Human factors in health and social care.
Spranzi Francesca. Reflecting on why surgical swabs are being left behind and exploring how this could be prevented (2021). British Journal of Midwifery. https://doi.org/10.12968/bjom.2021.29.6.310
Hignett, S., Jones, E. L., Miller, D., Wolf, L., Modi, C., Shahzad, M. W., Buckle, P., Banerjee, J., & Catchpole, K. Human factors and ergonomics and quality improvement science: integrating approaches for safety in healthcare. BMJ quality & safety, (2015). 24(4), 250–254. https://doi.org/10.1136/bmjqs-2014-003623
Holden, Richard J et al. SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. Ergonomics vol. 56,11 (2013): 1669-86. doi:10.1080/00140139.2013.838643
Waterson, Patrick et al. Remixing Rasmussen': The evolution of AcciMaps within systemic accident analysis. Applied ergonomics vol. 59, Pt B (2017): 483-503. doi:10.1016/j.apergo.2016.09.004
White Paper on Human Factors in Barrier Management, the Chartered Institute of Ergonomics and Human Factors (CIEHF, 2016)
Guidance on the design of effective work procedures. The Chartered Institute of Ergonomics and Human Factors (CIEHF, 2020)